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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,691	11/05/2001	Mircea Alexandru Mateescu	6670/0K000US0	9775

7590

02/10/2005

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EXAMINER

MONDESI, ROBERT B

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/021,691	MATEESCU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-14 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

This Office action is in response to the amendment filed November 22, 2004.

**Claims 1, 3-14** as drawn to elected Invention I are currently pending and are under examination.

### ***Maintenance of rejections***

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 3-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gokhale, et al. in view of Atanasiu, R .et al.

This rejection was explained in the previous Office action.

#### ***Claim Rejections - 35 USC § 112***

**Claims 1, 3-14** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was explained in the previous Office action.

### ***Double Patenting***

**Claims 1 , 3-14** are provisionally rejected under the judicially created doctrine of double patenting over claim 2-3, 6-15 of copending Application No. 10/012,730. This is

a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The present application is a composition comprising of a therapeutically effective amount of a mixture of pyruvate, at least one antioxidant, at least one lipid and ceruloplasmin. The composition of application 10/012,730 also comprises a therapeutically effective amount of a mixture of pyruvate, at least one antioxidant, at least on lipid (**claim 6**) and ceruloplasmin (**claims 2-3**).

***Response to applicant's arguments***

In regards to the rejection of **claims 1 and 3-14** under 35 § USC 103 as being unpatentable over Gokhale in view of Atanasiu, the applicants have simply cited the criteria for determination of obviousness in their response and have failed to address any of the arguments presented previously in the rejections or in response to applicants previous arguments, therefore the examiner has no choice but to restate the previously presented arguments.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies, , treatment of heart oxidative stress, is not recited in the rejected claim(s),. Although the claims are interpreted in light of the specification, limitations from the specification are

not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also the applicants' arguments are not probative in view of the composition of the invention since intended use does not materially change composition. See *In re Best* 562 F.2d 1252, 1254, 195USPQ 430, 433 (CCPA 1977).

**Claims 1 and 3-14** are broad claims that do not commensurate within the scope of the synergistic activity of the mentioned components of the composition of the invention. However, In view of figures 3A and 3B the examiner acknowledges the presence of unexpected results that are not constitutive of obviousness for the specific amounts of pyruvate, antioxidant lipid and ceruloplasmin used in the experiment (Triad (0.16X) and CP (0.5 $\mu$ m)). An amendment to claims, narrowing the claims to the specific amounts of Triad and CP that caused the unexpected activity, will overcome the rejection.

In regards to rejection of **claims 1, 3-14** under 35 USC § 112, first paragraph the applicants state that the meaning of the expression "functional derivatives of Ceruloplasmin" is obvious to anyone skill in the art and that it is well established by the law that when one has to interpret some expression in the claims they may refer to the specification. The applicants state further that the specification provides a suitable definition of this expression in paragraph bridging pages 10 and 11, and in subsequent paragraph of the specification, which gives further details of the meaning of this expression.

The examiner would like to state that perhaps the applicants have confused the rejection. The rejection of claims 1, 3-14 under 35 USC § 112, first paragraph was not

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made in regards to the indefiniteness of the claims. As the rejection was previously described in the previous Office action, the rejection of the claims is due to lack of description of "functional derivatives of Ceruloplasmin", meaning that there is, no description of the genus claimed by the applicants. Only Ceruloplasmin itself has been described in the specification and no other functional derivative or variant has been described and therefore the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is quite different than simply having to define the **meaning** of "functional derivatives of Ceruloplasmin".

***New Claim Objection(s)***

**Claim 1** is objected to because of the following informalities:

The applicants amended **claim 1** in amendment filed February 23, 2004 to include the phrase "cardioprotective", examiner believes that this is an error and the intended phrase is "cardioprotective".

Appropriate correction is required.

***Conclusion***

No claims are allowed

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

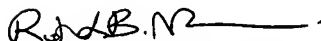
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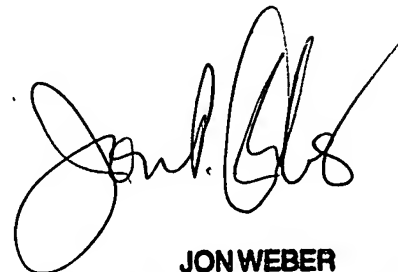
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert B. Mondesi  
Patent Examiner  
Group 1653

  
**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**